Coalition of *A*ccredited *L*aboratories

Comments on the Proposed Amendment to the Recycled Water Policy – Attachment A

Presented by David Kimbrough, Ph.D., Chair

June 19, 2018

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We would like to thank the Board for this opportunity to present our concerns in regards to the Proposed Amendment to the Recycled Water Policy and in particular Attachment A.

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- CAL represents both Publically Owned and Privately Owned Laboratories, from the Very Large to the Very Small
- CAL does not have a Position on the Use of Recycled Water as such
- CAL does however have Positions on the Laboratory Issues Raised by Attachment A

Background

Coalition of Accredited Laboratories

CAL

DRAFT AMENDMENT TO THE RECYCLED WATER POLICY
5/9/2018

ATTACHMENT A

REQUIREMENTS FOR MONITORING CONSTITUENTS OF EMERGING CONCERN FOR RECYCLED WATER

The purpose of this attachment to the Policy is to provide direction to the regional water boards on monitoring requirements for constituents of emerging concern (CECs) in recycled water. The monitoring requirements and criteria for evaluating monitoring results are based on recommendations from a Science Advisory Panel[1].

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- Attachment A is about Monitoring & Analysis of Contaminants of Concern in Recycled Water
  - This is an area of interest to CAL
  - It is also an area where CAL members have considerable expertise
  - CAL would like to Offer to Work with the State Board on an On-Going Basis in an Advisory Capacity on this Topic

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1 QUALITY ASSURANCE AND QUALITY CONTROL

This section is to ensure laboratories conducting CEC monitoring generate data of known, consistent, and documented quality and to verify that the laboratory can meet the required reporting limits. Quality assurance and quality control measures shall be used for both collection of samples and laboratory analysis work. The recycled water project proponent or recycled water producer shall develop a quality assurance project plan that is consistent with this Policy. The quality assurance project plan shall be submitted to and approved by the regional water board prior to beginning any sampling and analysis.

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- CAL Supports the General Approach Expressed in Attachment A
  - Each Recycled Water Project Should have a Quality Assurance Project Plan (QAPP)
  - Each QAPP Should Be Approved by the Regional Board
  - QAPPs have been used for many years in variety of Regulatory Situations Successfully
  - This is a Very Good Approach in General

- CAL also Believes that Attachment A Could be Improved Considerably in the Details
  - Reinventing the wheel with new terms.
    - Already established protocols
    - USEPA / SWRCB
  - Accreditation
    - Rely on CA ELAP Accredited labs – using AB1438
    - TNI/ISO – remove reference to unapproved standards
    - Establish Protocols for the use of unapproved methods for CEC
  - Reporting limits
    - Define: E.g DLRs,
    - Verification Procedures

- Quality Assurance Project Plans
  - It is important to note that QAPPs have not historically been used for Routine, On-Going Regulatory Compliance Monitoring programs
  - Drinking Water program have rarely used them.
  - Traditionally QAPPs have been used for Specific Time Limited Investigations or Projects with a Discreet Beginning and End
  - Clean-Up Operations at a Superfund Site or Investigation into a Watershed for a particular purpose are more typical for the use of QAPPs
  - That does not Preclude their Use but It Does Mean that this is New Territory

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1.1 Quality Management Systems

The recycled water project proponent or recycled water producer shall confirm and be able to produce documentation that a laboratory used to perform analysis of CECs required under this Policy has a laboratory quality management system in place that meets the requirements described in 1.1.1 or 1.1.2 below. The requirements in 1.1.1 and 1.1.2 describe equivalent quality management systems. The recycled water project proponent or recycled water producer shall make such documentation available if requested by the State Water Board or regional water board. A laboratory must comply with the requirements of either 1.1.1 or 1.1.2:

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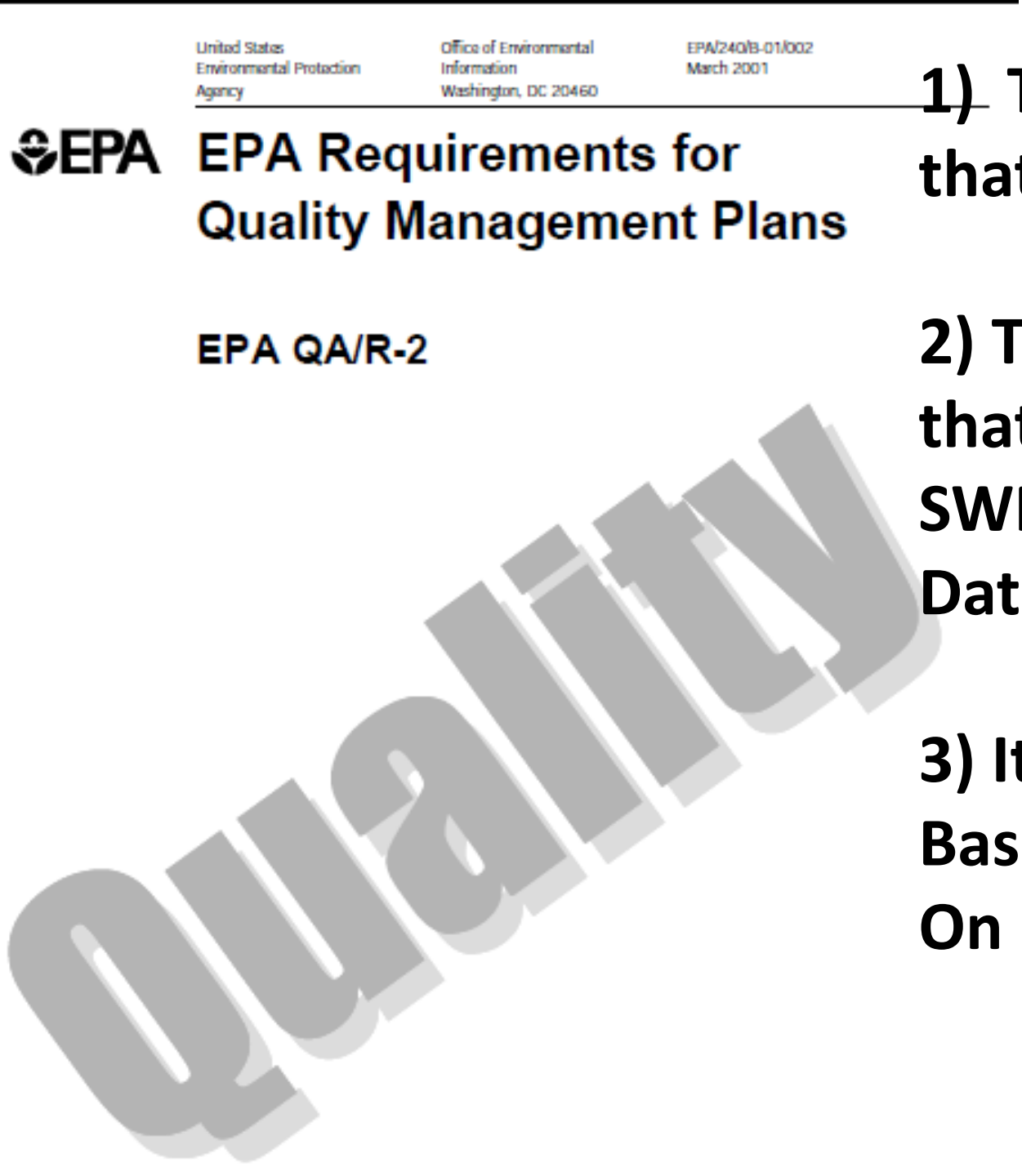
1.1.1 Comply with the management and technical requirements applicable to their operations in accordance with The National Environmental Laboratory Accreditation Conference Institute (TNI) 2016 Standard Volume 1, Module 2 – 7, with the following exceptions:

1.1.1.1 Volume 1, Module 2, Section 4.1.7.2(f) – Technical Manager Qualifications; and

1.1.1.2 Volume 1, Module 2, Section 5.2.6 – Additional Personnel Requirements.

1.1.2 Develop and implement a quality assurance program to ensure the reliability and validity of the analytical or bioanalytical data produced by the laboratory. As evidence of such a program, the laboratory shall develop and maintain a quality manual.

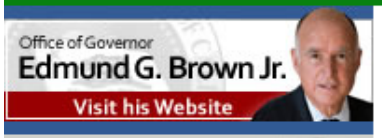
- Attachment A is Largely Limited to Some Laboratory Issues
  - QAPPs Need to Include the Entire Project, not Just Laboratory Issues
  - QAPPs Need to be Part of a Larger Quality Management Plan (QMP)
  - QMPs and QAPPs are Well Defined in Both USEPA and SWRCB Literature and History
  - Attachment A Makes no Reference to this Literature or History
  - Attachment A Does not Discuss Laboratory Accreditation
  - Attachment A Includes Unnecessary TNI and ISO Language



1) This is the QMP that USEPA Uses

2) This is the QMP that many of the SWRCB & DTSC Data users also use

3) It makes sense to Base Attachment A On USEPA QMP



- CalEPA
- State and Regional Water Boards' Map
- Board Priorities
- Laws/Regulations
- Make a Payment
- Plans/Policies
- Programs
- Decisions Pending and Opportunities for Public Participation

Report an Environmental Concern

Quality Assurance/Quality Control - QAPP

WHAT IS A QUALITY ASSURANCE PROJECT PLAN (QAPP)?

A QAPP contains 24 elements that describe a project's goals, data needs and assessment, responsible individuals, quality assurance plan, quality control measures (i.e. measurement quality objectives (MQOs)), and reporting deadlines.

A QAPP is project-specific and is designed to provide the type and quality of data required to answer questions posed by the project.

For more information on MQOs, see (FAQs).

QAPP DEVELOPMENT RESOURCES

WATERBOARD GUIDANCE RESOURCES

- QAPP Review Checklist
- Example QAPPs
- QA Help Desk
- For more information see FAQs

USEPA GUIDANCE DOCUMENTS

- Quality Management Tools - QA Project Plans
- Guidance for Quality Assurance Project Plans
- EPA Requirements for Quality Assurance Project Plans
- Agency-wide Quality System Documents

SWAMP
Surface Water Ambient Monitoring Program

Final	May 2017

Quality Assurance Program Plan

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- There are 24 Elements to a QAPP
  - Most of a QAPP has nothing to do with Laboratories
  - Attachment A is overwhelmingly focused on Laboratories and Does not Include Even Half of those Elements
  - Without the Broader Context of a QMP and QAPP, Laboratories Cannot Perform their Jobs Adequately

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Report an Environmental Concern

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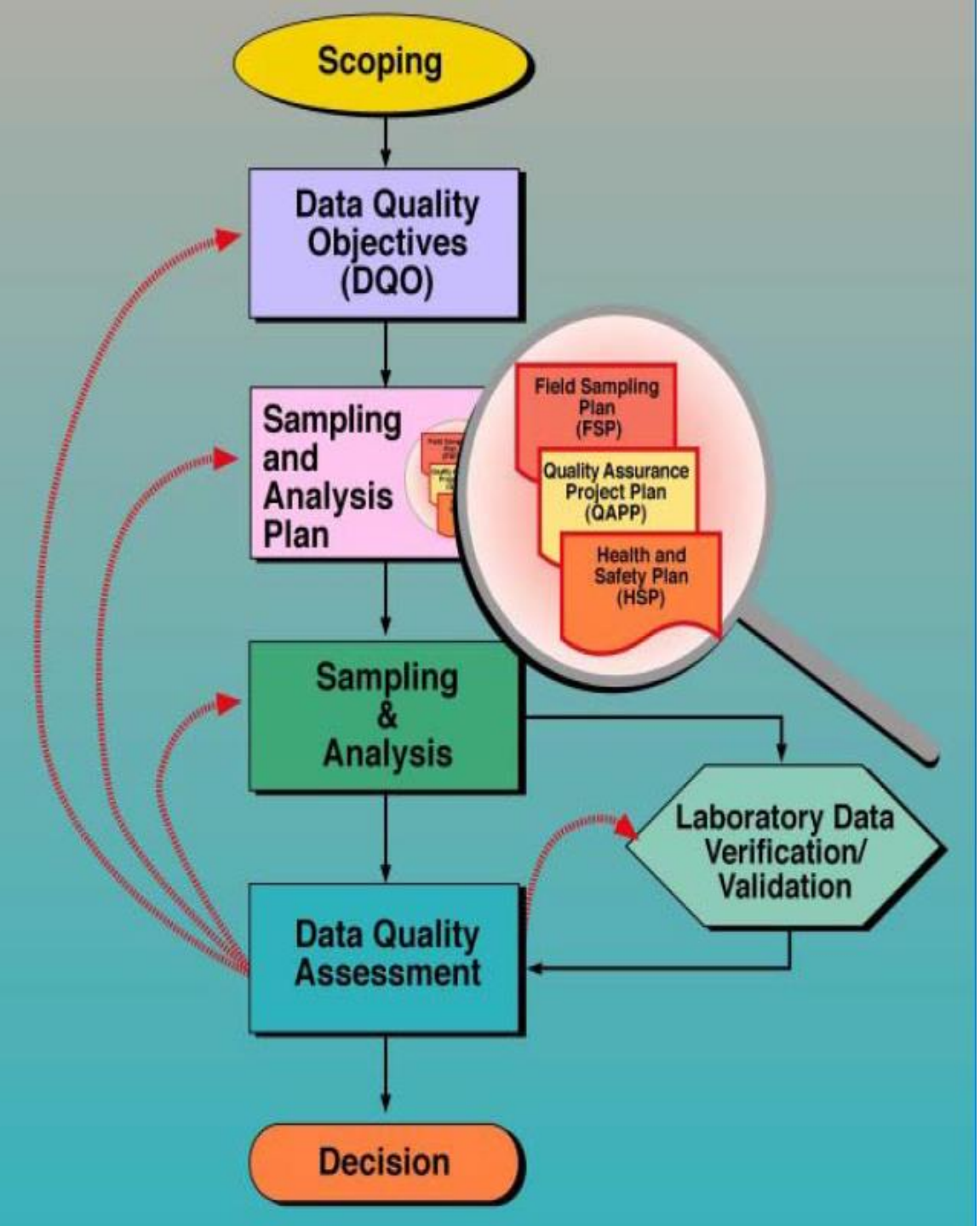
Quality Assurance / Quality Control - 24 Elements of a QAPP

(USEPA guidance)

24 Elements of a QAPP	
A1 – Title and Approval Sheet	B4 – Analytical Methods
A2 – Table of Contents	B5 – Quality Control
A3 – Distribution List	B6 – Instrument/Equipment Testing, Inspection and Maintenance
A4 – Project/Task Organization	B7 – Instrument/Equipment Calibration and Frequency
A5 – Problem Definition and Background	B8 – Inspection/Acceptance of Supplies and Consumables
A6 – Project/Task Description	B9 – Non-direct Measurements
A7 – Quality Objectives and Criteria	B10 – Data Management
A8 – Special Training/Certifications	C1 – Assessment and Response Actions
A9 – Documentations and Records	C2 – Reports to Management
B1 – Sampling Process Design (Experimental Design)	D1 – Data Review, Verification and Validation
B2 – Sampling Methods	D2 – Verification and Validation Methods
B3 – Sample Handling and Custody	D3 – Reconciliation with User Requirements



1) The Starting Point of a Quality System Is the Data Users and DQOs

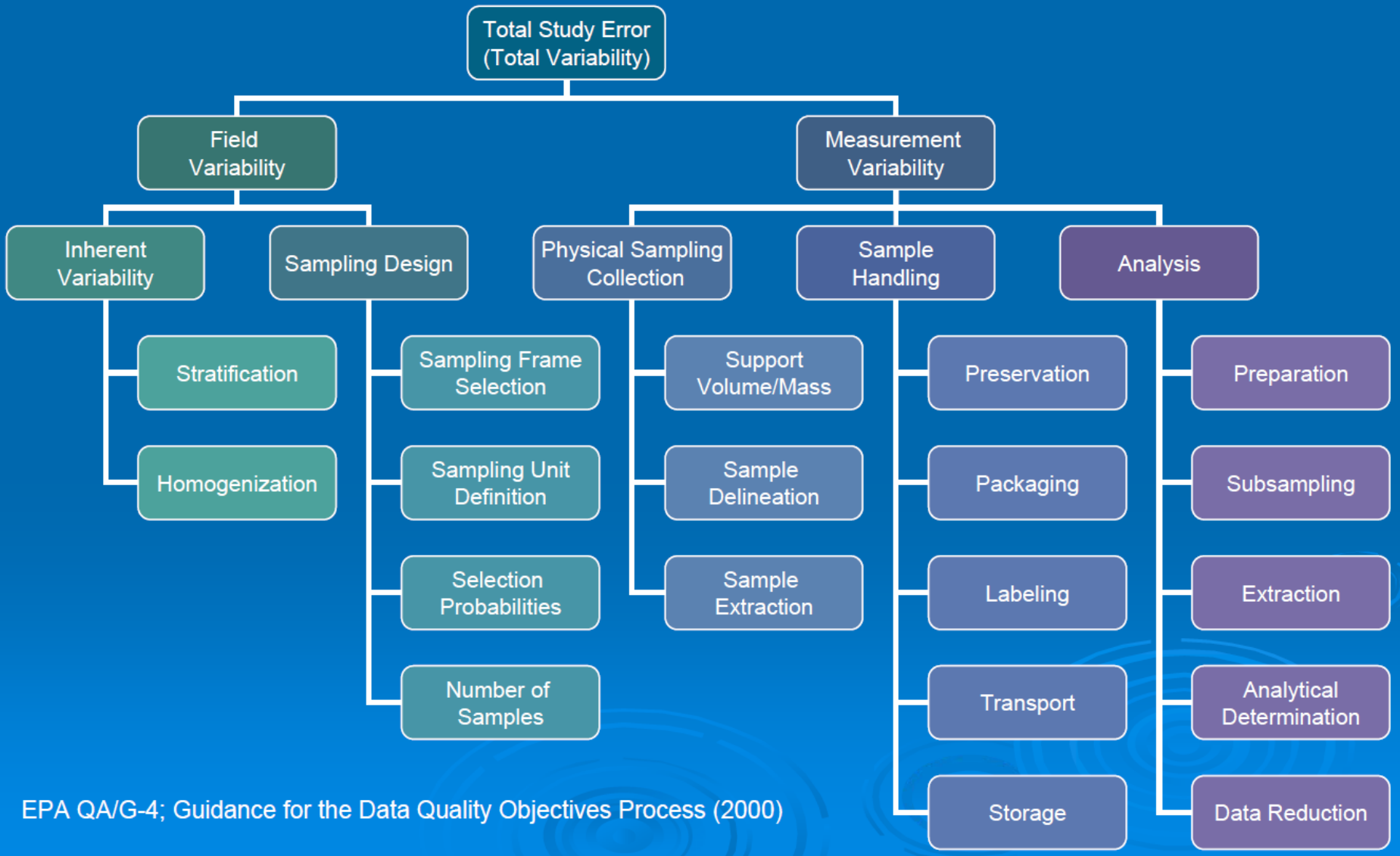
2) The Axis on which a QAPP Turns is the DQA

3) Laboratory work is only one Part of the Quality Management Plan, Not Even the Majority

Data Quality Indicators

DQI	Examples
Precision	Sample Replicates, MDL Studies
Accuracy (bias)	Sample Spikes, Reference Materials
Representativeness	Sample Replicates, Total # of Samples, PAEP
Comparability	Intercomparison Studies, Consistent Methods
Completeness	Data Verification (# of samples with results)
Sensitivity	MDL Studies, Calibrations

Components of Total Study Error



EPA QA/G-4; Guidance for the Data Quality Objectives Process (2000)

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- Attachment A should be Based on USEPA & SWRCB QMP and QAPP Requirements
  - Attachment A needs to set the Requirements for an Entire QAPP, not just Parts
  - TNI and ISO Language should be removed as it Unnecessary, Confusing, and Cumbersome
  - This Gives Uniformity with Existing Federal and State Programs
  - This also Better Achieves the Objectives of the Recycled Water Policy

- A Single State Wide Quality Management Plan
  - Identify Data Users and Decision Makers
  - Data Quality Objectives
  - Data Quality Indicators
  - Measurement Quality Objectives
  - Model Sampling and Analysis Plan (“SAP”)
  - Model Data Quality Assessment (“DAQ”) Process
  - Project Assessment and Evaluation Plan (“PAEP”)
  - This Gives Uniformity with Existing Federal and State Programs
  - TNI and ISO Language should be removed as it Unnecessary, Confusing, and Cumbersome

Accreditation of Laboratories

- The Current Language of Attachment A Does not Address Accreditation of Laboratories
- The Proposed Recycled Water Policy Amendment Will Not Work Without Laboratory Accreditation
- The Proposed System Described in Attachment A seems to be as a Sort of Substitute Quasi-Accreditation Program
- Most of These Tests and Analytes are New and There is Little History on which Laboratories can Draw upon to Implement this Policy.
- Given the Significance to Public Health of the Use of Recycled Water and the fact there is Little Track Record for these Methods, Anything Less than Full Laboratory Accreditation Will Not Suffice
- A QAPP is not a Substitute for Laboratory Accreditation

- Reporting Limits
  - Reporting Limits are Not Currently Defined
  - The Best Model is the Detection Limit for Reporting which is used by the Division of Drinking Water
  - This is the Lowest Concentration that 80% of Laboratories can Measure with a Fixed Accuracy (e.g. ± 30% for Perchlorate)
  - The Best Model for Verification of the DLR is the USEPA's Disinfection By-Product Rule
  - With Each Batch, a Laboratory Reagent Blank is Analyzed and the Measured Value Must be less than the DLR
  - With Each Bach, a Laboratory Fortified Blank is Analyzed at or below the DLR and the Measured Value Must be equal to the DLR ± the Acceptance Limit.
  - This Cannot be Done without Laboratory Accreditation

1,4-Dioxane

- The QMP could identify that the State Board and RWPP as the PDU and DM need to monitor for 1,4-Dioxane as it is a suspected human carcinogen which is known to be a contaminant in groundwater and is known to occur in recycled water.
- DQOs and DQI overall for would be Precision, Accuracy, Representativeness, Comparability, Completeness, and Sensitivity.
- For Laboratories, MQOs for precision can be assessed by using sample replicates. Accuracy by matrix spikes and reference materials. Sensitivity can be assessed through DLR Verification
- The PAEP and SAP can identify USEPA Method 522 or SW-846 Method 8270c as appropriate methods.
- ELAP can offer accreditation to laboratories for these methods for this analyte for this QMP
- SAP could include the use of Field Blanks (1 per sampling event, results less than the DLR), Field duplicates (1 per sampling event, Relative Percent Difference (RPD) < 30%), calibration curve, continuing calibration checks, laboratory reagent blanks, laboratory fortified blanks, matrix spike, and matrix spike duplicate (frequency and acceptance criteria as per the method).

Conclusions

Attachment A

- Requiring a QAPP for each Recycled Water Project is a Good Idea
- Attachment A is Incomplete, it at best describes a only a small part of a QAPP
- Attachment A Should be based on USEPA and SWRCB QAPP and QMP Requirements and Include the Entire Recycled Water Project
- A Robust Laboratory Accreditation process is Critical to the Success of this Effort


Application for Certification
Environmental Laboratory Accreditation Program

PART A
LABORATORY INFORMATION

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Thank you